High- quality patents for emerging science and technology through external actors: Community scientific experts and knowledge societies

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Abstract

This article explores one type of administrative mechanism to achieve high-quality patents: Article 115 of the European Patent Convention, which permits the inclusion of third parties to provide input to the prior art search and to communicate relevant information to the examiner in charge. Our empirical research analyzes the field of human genetic inventions. The empirical findings here show that third parties usually participate only after patents have been granted. Between 1999 and 2009, only a limited number of human gene patent cases made use of third-party, pre-grant interventions. There is thus an imbalance between third-party participation in the pre- and post-grant phase of patent prosecution, and we urge for greater participation of knowledge communities in the search and examination process. Europe should create a funnel for participation through advisory bodies and learned societies, which would allow judicious consideration of the search and examination, with a resultant improvement in patent quality.

Keywords: Third party participation, prior art search, patent prosecution, European Patent Convention

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1. Introduction

The number of patent applications and patents granted has doubled over the past two decades. The emergence of new scientific and technological fields with little "prior art" has overwhelmed the ability of patent authorities throughout Europe to assess whether inventions meet the patentability requirements (novelty, industrial applicability, and inventive step). This increase in patent activity has also raised the issue of patent quality. Among the main concerns raised by policymakers, the business community, practitioners, academics and examiners is the extent to which patent examiners have adequate resources to perform their search and examination tasks. A careful search and examination procedure reduces the need to review patents when they are opposed, cuts down on litigation and contributes to the validity of patents that are granted. There are too few patent examiners which, coupled with the shortage of time available to search and examine patent applications, inflation in the number of filings, rapid developments in emerging fields of science and technology, have all increased uncertainty in the interpretation of the patentability criteria, and thus the quality of patents.

Ensuring stable and high-quality patent rights is the most vital consideration for any patent office. It is acknowledged that high-quality patents[1] are important for innovation, the diffusion of knowledge and economic growth. Concern for patent quality is not new, nor has it gone unaddressed by scholars (Burke and Reitzig, 2007; Edfjäll, 2007; Elsmore, 2009; Philipp, 2006; Shang, 2009; van Pottelsberghe, 2009; Wagner, 2009; White, 2004) and policy-makers (Cowan et al., 2007; European Commission, 2008; European Patent Office, 2009). However, there has been little analysis of the patent quality mechanisms used in patent offices. Mechanisms to achieve high-quality patents can follow the division of the legislative, executive and judicial functions of patent matters among separate and independent bodies. This article focuses more narrowly on the administrative mechanisms dealing with third-party participation in the patent process at the European level. In this jurisdiction, the principal process leading to the grant of a patent is search and examination. Article 115 of the European Patent Convention (EPC) permits the inclusion of third parties to provide input to the search of prior art and communicate relevant information to the examiner in charge.

The aim of this article is to understand and assess how and when third parties may participate during the patent prosecution process. In particular, we provide an answer to the following research questions. First, to what extent have the current patent examination practices and the "peer-to-patent project" been effective in increasing patent quality? Second, how can external actors, specialized in the field contribute by providing information about the patentability of new inventions and be officially recognized by patent agencies?

Our empirical research analyzes the field of human genetic inventions, within the area of biotechnology. In our view, biotechnology differs considerably from other sectors, in that it is the only domain to have a unified, sector-specific patent law. Moreover, the

[1] High-quality patents should meet patentability requirements, contribute to the state of the art, offer scientific/social benefit, and stand up to the most rigorous challenges in court.

Biotechnology Directive 98/44/EC has brought new types of human intervention into the patent arena. To identify patent infringement cases involving human gene patents, we searched the Westlaw International Database, the EPO Board of Appeal Database (EBOA), as well as the esp@cenet network and the Register Plus service provided by the European Patent Office (EPO). The data retrieval strategy included the International Patent Class "C12"[2] and the keywords "human gene" *or* "DNA" *or* "gene sequence" *or* "human stem cells", *and* "gene & patent & opposition" in the claims or patent application abstract, in the notices of opposition that had been filed, and in the decision that had been made.

The empirical findings here show that third parties usually participate only after patents have been granted. Patent decisions for the period 1999 and 2009, emphasize that only a limited number of human gene patent cases made use of third-party, pre-grant interventions. There is thus an imbalance in third-party participation in the pre- and post-grant phase of patent prosecution, and the paper urges that knowledge communities should participate in the search and examination process. We recommend the involvement of two types of knowledge communities: learned societies and advisory bodies that specialize in particular emerging scientific and technological domains.

New technologies are no longer regarded as entirely passive entities developed by inventors and used by customers; rather, they comprise complex actors and networks, involving laboratories, patients, technicians, families, geneticists and other stakeholders. This premise was tested empirically in the research presented here, which shows that certain stakeholders participated in the creation of the patent biotechnology regime, but that these stakeholders differ from the new stakeholders who participate in the pre- or post-grant phase. For example, in 2007 and 2008, the EPO's Opposition Division revoked several patents on human genes. The decision was a victory for the French Association of Research Institutes and Hospitals, Greenpeace and a number of genetic societies and patient organizations, scientific associations, cancer researchers and special interest groups.

There are several established advisory bodies in the European biotechnology field, both at national and European level (*e.g.* National Bioethics Committees, National Socieities on Human Genetics, National Socieities of Biotechnology, the European Group on Ethics in Science and New Technologies), as well as learned societies (such as the European Society of Human Genetics, the European Federation of Biotechnology). In this article, the policy recommended is instead to following the American approach to third party involvement: Europe should create a funnel for participation through advisory bodies and learned societies, which will allow the search and examination process to be conducted judiciously, with a consequent improvement in patent quality.

The remainder of this article is organized as follows. Section 2 highlights the current European patent examination system and reviews the literature on external actors in patent prosecution. Section 3 deals with the "peer-to-patent" pilot programme which has been established by the United States Patent Office (USPTO) to encourage public

[2] International Patent Class "C12" includes patents in the field of biochemistry and genetic engineering.

participation on “prior art” inventions. Section 4 empirically investigates the involvement of actors in the search and examination process as related to recent human gene patents. In this section we also explore the potential that certain external actors, specialized in the field, have to provide information on biotechnology inventions and gene technologies, thus complementing the work of the patent examiners in the search and examination phase. Finally, Section 5 makes policy recommendations and concludes the article.

2. The European Patent System and the Patent Quality Crisis

In Europe, patents are regulated by the EPC, a multilateral treaty which institutes the European Patent Organization (EPOrg) and provides an autonomous legal body for granting European patents: the European Patent Office. The EPO is the centrepiece of the patent system in Europe and is constituted by 36 Contracting States, including the 27 EU Member States. In line with Article 52 (1) of the EPC, the EPO grants patents to inventions that are new at the time the patent is filed, involve an inventive step that is not obvious to a person skilled in the art, and generate useful outcomes (Langinier and Moschini, 2002). After the patent application is filed, the EPO’s Search Division draws up a Search Report relevant to the subject matter of the patent claim. Following Rule 44 (1) and (2) EPC, the search examiner should indicate in the Search Report which documents (available to the EPO at the time the Search Report is conducted) and claims are considered to be relevant to decide whether the claimed invention is new and involves an inventive step. The Search Report is performed by the examiner and aims at finding all prior art information relevant to the patentability of the invention (Guellec and van Pottlesberghe, 2007). In addition, patent applications may undergo substantive examination by the Examination Division which is composed of three technical examiners. During this stage the Examining Division conducts an additional search of the patent application and claims, by looking at relevant prior art from other related applications or in other technical fields that are covered by the initial search (Akers, 2000).

In addition, Rule 42 (1) (b) EPC requires that patent applicants indicate the background art in their patent application, which as far as known to the applicant, can be regarded as useful information for the examiners to understand the inventions, and draw up the European search report and examination. However, EPC provisions are not interpreted as placing an obligation on the applicants to communicate to the EPO examiners every item of prior art information relevant to the application. In many cases when applicants are not sure about the prior art, they wait for the examiner’s search result and then consult the prior art themselves. By contrast, when the applicants are well informed about prior art, they submit every item of information of which they are aware. In this way, examiners end up faced with either a limited number of references or dozens of marginal references (Thomas, 2001). This, coupled with an increased number of patent applications (from about 20,000 in the early 1980s to more than 190,000 in 2005), the pressure to work faster to reduce the patent pendency rates, and the severely

limited employee schedule (10-15 hours per application[3]) means that patent examiners often fail to consider all references. Furthermore, patent offices have also witnessed an increase in patent applications that focus on technology fields (i.e. biotechnology inventions, gene patents, or computer programs) with sparse resources available for their examination (Duane, 2008). This has placed further stress on patent examiners since information on such inventions might be found in certain unwritten documents, oral or written disclosures known only to certain parties (third parties) which have knowledge of or operate using these new technologies. In this way, new technological developments have come to challenge the examiners' ability to acquire adequate information to examine patents. As Noveck (2006) claims, in some cases there is either too little information about prior art (i.e. computer software patents) or too much (*i.e.* biotechnology), and patent examiners lack the means to sift through it.

To supplement the ability of the EPO examiners to locate relevant information on patent applications, the EPC has laid down Article 115, which provides that after the publication of the European patent application, third parties can communicate certain information or documents to the examiner in charge concerning the patentability of the invention for which an application has been filed. No fees are required for the submissions of observations and the person filing an observation may not be a party to the proceedings before the EPO. Third-party observations are also communicated to the applicant, who may comment on them. In this way, the provisions of Art.115 EPC provide mechanism by which relevant prior art undisclosed to the EPO examiners may be included in the patent prosecution proceedings. In effect, such observations may also supplement the scope of the EPO examiners' search and reduce their workload when locating prior art. The EPO's function in relation to third party observation is to review the patentability of the claimed inventions and determine whether the application can be upheld after the submission of observations (Harmon, 2006).

The idea underlying the pre-grant observation process is to improve patent quality, but the mechanism still continues to be used rather infrequently (*for details see* Section 4). Akers (2000) indicates that a possible disincentive for some parties (especially private companies) to file observations may be their commercial and competitive interests. Prior-art observations may forewarn the applicant of the competitor's interest, so third parties wait until a patent has been granted before filing their opposition.[4] EPO's one-way communication with third parties is also a disincentive for these parties to file observations. Guellec and van Pottelsberghe (2007) claim that after observations are

[3] The number of hours spent examining each patent claim has more than halved since 1992, from 23.8 hours in 1992 to 11.8 hours in 2001.

[4] According to Arts. 99-105 EPC, third parties can file an opposition within a period of 9 months after the EPO has decided to grant or refuse the application. Similar to the search and examination procedure, oppositions can be filed by any person (natural or legal). The notice of opposition is examined by the Opposition Division at EPO. The conclusion of the opposition proceedings can lead to the following outcomes: the opposition is rejected and consequently the patent is upheld without amendment; the patent is revoked; or the patent is amended (Art. 101 EPC). According to Harhoff et al. (2007), it takes an average of 1.9 years to sort out an opposition case. The opposition procedure takes approximately 2.2 years if the patent is revoked and approximately 4 years if it is amended. The cost of opposition ranges between €15,000 and €25,000 for each party. *See also*: Harhoff, D. et. al. "The strategic use of patents and its implications for enterprise and competition policies" (2007). Available at: http://www.en.inno-tec.bwl.uni-muenchen.de/research/proj/laufendeprojekte/patents/stratpat2007.pdf [Accessed September, 2010]

received, the Examination Division adds them into the file and decides whether any of the observations (which provide better arguments for the case) should be considered, but third parties are not informed of any further action the Division takes in response to their observations. Indeed, as we shall see in the next sections, patent examiners do not pay considerable attention to third-party observations, even when numerous filings are made. Patent examiners' decision to grant or revoke a patent application is not much affected by the observations of third parties (*see* Table 1.3). As a result, patent examiners' dialogue with other experts is quite underdeveloped. According to Hagel (2008),[5] this practice has resulted in patent examiners suffering from the "ivory tower" syndrome. Insufficient use of Art. 115 EPC has led to the "isolation" of patent examiners from the real world and to increased legal uncertainty in the protection of new, emerging technologies. For all these reasons, the patent office has been increasingly challenged by litigation about the quality of patents issued, which reveals the weaknesses of the present patent assessment system. Current estimates by Holzer (2005) and Harhoff (2009) indicate that the number of patent opposition cases in Europe is about 1,260 per year, 600-700 instances of which relate to European patents. Most of the litigation comes from electrical engineering (165 cases), pharmaceuticals (149 cases),[6] organic chemistry (including biotechnology with 141 cases), mechanical engineering (139 cases) and process engineering (113 cases).

3. Mechanisms for Enhancing Patent Quality: Providing an Inclusive Patent Prosecution Process

The patent prosecution problems are commonly acknowledged, and a number of patent scholars have recently proposed various mechanisms to improve the quality of patents and establish an inclusive patent prosecution process. In his recent work "*Understanding of Patent Quality Mechanism*", Wagner (2009) argues that patent law is a specialized field with many active players. Focusing on the multi-actor characteristics of patent law, Elsmore (2009) and Wagner (2009) claim that high-quality patents will be issued only if patent offices balance the interests of active and passive users, and legislate an "open review procedure", which would allow third parties to challenge patents after issue. Burke and Reitzig (2007), Edfjäll (2007) and White (2004) argue that the information flow among actors is important since it allocates additional resources to patent authorities, and ensures ongoing deliberations on the patentability of a variety of subjects. Information on patent claims contributes to the patents' clarity and leads to a more cost-effective examination process (Cowan et al., 2007). Patent offices should therefore allocate additional resources to examiners and ensure ongoing deliberations on the patentability of various subjects. Other scholars state that patent examiners' access to scientific and patent literature, and collaboration with commercial patent

[5] Staff Union of the European Patent Office. "Interview with Francis Hagel," February, 2010.
Available at: http://www.suepo.org/public/interviews/ex08013cp.pdf [Accessed March, 2010]

[6] According to the European Commission sector inquiry into EU pharmaceuticals markets, companies initially reported a total of 698 separate patent lawsuits. However, a final judgment was reported in 149 of the suits (84 initiated by the generating company and 65 by the originating one), and 549 cases were reported as pending or settled.
See: European Commission: Competition DG. "Pharmaceutical Sector Inquiry - Preliminary Report" (2008).
Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf
[Accessed March, 2010]

information providers or other institutions specialized in protecting certain industries, also provides high-quality outcomes (Philipp, 2006; White 2004).

Scholars suggest that the multi-actor involvement and information flow are crucial to improving patent quality and ensuring legitimate outcomes. However, most of these mechanisms encourage participation after the decision to grant/revoke a patent has been made. According to Noveck (2006), ex-post solutions, such as "post-grant administrative review or proposals to revisit the scope of patentable subject matter and obviousness", cannot work if the patent system lacks appropriate mechanisms for obtaining the requisite information on patentability. Opposition and invalidity proceedings cannot make a significant contribution to improving patent quality; collusion between prior art holder and the applicant may reduce the chances that granted patents will be invalidated in opposition proceedings (Thomas, 2001; SUEPO, 2002). However, while third-party challenges, and post-grant oppositions in particular, have periodically been studied by scholars (e.g Holman, 2008; Harhoff, 2009; van Pottelsberghe, 2009) and policy advisors (e.g. Cowan et al., 2007; Cohen et al, 2008), systematic analyses of the "pre-grant" observations introduced by third parties are rare. In our view, post-grant opposition procedures cannot build trust, legitimacy and quality within the current system if relevant stakeholders are not involved prior to a grant of protection to the claimed inventions.

3.1. External Actors: Added Value to the Patent System

Current trends in innovation reveal that in addition to traditional regulatory actors (i.e. government and private business), the informal actors of social control (i.e. laypeople and experts, NGOs) also influence the framework within which technology is regulated, at both the national and international level (Schrell et al., 2007). Since new technologies, such as biotechnology innovations, genetic testing or diagnostic methods, have become crucial to the development of public health and government plans to expand the knowledge economy and boost competitive strategies, there is a need for the innovation regulatory framework to create a balance among these various needs and actors. While advocates of technocracy argue that technical experts are more able to exercise professional judgment on new technologies and determine what is in society's best interests, others argue that such a focus is at odds with the principles of deliberative democracy (Brooks and Johnson, 1991; Picciotto, 2001). Modern societies should provide new forms of democracy which lead to improved decision making through communicative interaction and information, and an engagement between the social consensus and risk perception, both before and after decisions have been made. In respect to the innovation process, Brownsword (2008) argues that an effective innovation system can be achieved only if the regulation of new inventions involves a variety of actors in every regulatory phase. It is only in the first phase that regulators and other actors are provided with the opportunity to "control, confine and channel ex-ante" the operations and successful practice of inventions (Brownsword, 2008, p. 18).

The academic literature on patent quality adds to the participatory debate, claiming that the "chain of innovation" consists of various actors that are affected by the "existing or potentially granted patents" and it is crucial that patent offices ensure actor involvement

to providing relevant information both before and after patents are granted (Edfjäll, 2007). In this respect, Shang (2009) contends that the inclusion of third parties in the examination process provides added value to patent quality, since parties (i.e. the patent owner, the challenger and the patent office) have better opportunities to assess the validity of questionable patents and new technology inventions. Scholarly debate reveals that patent examiners have technical qualifications, but their reluctance to use outside expertise has led patent offices to rely unduly on centralized organs of expertise, turning the problem of patent quality into a one that mostly relates to difficulties in accessing the right information (Noveck, 2006). Thus, while a patent examiner might have to spend hours searching for prior art, experts in the field may know instantly whether an invention interlinks with earlier work or research. Along the same lines, Harmon (2006) argues that the contribution of outside expertise, in the form of the scientific community, can remedy the patent examiners' information deficit and provide the basis for reducing the shortcomings of numerous innovations.

Technological developments in the life sciences, biotechnology and especially plant biotechnology, cloning, and genetic testing, have added many other concerns to the examination process, such as the extent to which these inventions: a) meet the patentability requirements ; b) are industrially applicable; and c) meet with ethical and social principles. In particular, developments in gene technology have attracted the attention of numerous actors due to their socio-economic, health and research impacts. Gene patent applications differ from other inventions, since broad claims tend to form an intrinsic part of them, including information on nucleic acid sequences, fused cells, vectors, recombinant proteins, monoclonal antibodies that could subsequently be generated, etc. (Aymé et al, 2008, p.S6) [7]. There have been many debates that question the novelty, non-obviousness, and risk of these new technologies and their effect in undermining scientific research, medical advancement and patient care. Broad claims may prevent researchers searching for cures for genetic diseases or impose unnecessary constraints on competition and downstream innovation. These challenges have made the input of external actors even more vital in order to keep patent examiners up to date with such scientific and social implications as the inevitable biotechnological inventions and other derivative technologies may have. For instance, the controversy over BRCA gene patents and the Edinburgh patent on human embryonic stem cells give a clear picture of the impact that various external actors (*e.g.* research institutes, genetic societies, environmental agencies, political parties, pro-life groups, national governments), have had, not only translating public criticism into mandatory requirements for changing the regulatory framework of patent law, but also serving as a crucial mechanism for making examiners more aware of the patentability of inventions.

[7] According to the OECD definition, gene patents relate to one of the following four categories: "1) whole genes or parts of them, 2) proteins that the genes encode as well as their function in organisms, 3) vectors used for the transfer of genes from one organism to another, or 4) genetically modified cells or organisms used for the making of genetically modified products and the uses of genetic sequences or proteins for genetic tests". *See*: Gold, Richard and Carbone, Julia. "Appendix B: Detailed Legal Analysis of Gene Patents, Competition Law and Privacy Law. Innovation Partnership" (2008). Available from: http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Legal.pdf [Accessed August, 2010]

In one of its working papers "A *Quality Strategy for the EPO"* (2002), the Staff Union of the EPO concluded that high levels of patent quality will be achieved only if mechanisms for determining the patentability of inventions involve the collaboration of industrial research laboratories, the academic community, experts and laypeople, all of which are expected to assist examiners, broadening their views on patents and establishing systematic feedback on the quality of patent claims. "Exchange with the outside world" and inclusion of "expertise in areas that are not much represented in patent offices" are considered crucial mechanisms for improving patent quality (SUEPO, 2002; UK Nuffield Council on Bioethics, 2006). However, these reports do not explain how such expertise can be incorporated into the patent prosecution process. Exceptionally, in 2007 the USPTO for the first time launched a mechanism for incorporating third-party contributions to the substantial examination process by means of a web-based platform open to the community at large.

3.2. U.S. Peer-to-Patent: the Community Patent Review

The U.S. Peer-to-Patent project provides for online, prior-art screening in which third parties are able to contribute to the USPTO examination process. The aim of this project is to test whether peer review and third-party participation can deliver any improvements to the USPTO patent examination process (Kao, 2006). Under this system, the patent examiner is obliged to perform a full examination of patents, but third parties can provide additional prior-art information for two months after the patent application has been published. Third parties can submit a request for patent application review by registering it online on the U.S. Peer-to-Patent website. Thereafter they can post a reference or notice of prior art that they believe is relevant for assessing the patentability of specific patent application. Third-party references are launched on a public-view page where others are able to view and comment on them and vote for the most relevant references for the examiners to consider. In this way a peer reviewer will access the U.S. Peer-to-Patent programme "to rate patent claims, prior art submissions and other reviewers, and to comment on the patent or on specific prior art submissions" (Noveck, 2006, p.147). However, the USPTO will accept only those references and comments that gain the most votes from the users.

The U.S. Peer-to-Patent system provides an added value in: a) enhancing transparency and actor involvement within the patent examination process; b) assessing the body of knowledge that exists among the general public in regard to certain inventions; c) providing examiners with supplementary information, thus saving their time when making decisions on patent applications; and d) enabling third parties to prevent possible infringements of their rights before the patent is issued. Nevertheless, the system also has its shortcomings. To begin with, in common with many other open, web-based applications, the U.S. Peer-to-Patent system requires only the applicants' first and last names. This level of anonymity may lead to a lack of accountability and limit the range of valuable submissions. The possibility of "gaming" in patent procurement by favouring one type of application over another may also jeopardize the effectiveness of the self-monitoring, online peer-review process (Kao, 2006). Additionally, by allowing everyone to introduce knowledge on the prior art, the USPTO

may run the risk of exposing itself to a mass of prior art references, which risks making the very notion of patentability quite specious. The examiner will be able to reject patent applications on the grounds of "novelty or non-obviousness" based on combinations of various prior-art references, even for those inventions which might actually be innovative (Duane, 2008). According to the results of the first 11 months of the U.S. Peer-to-Patent pilot study,[8] the number of contributors registered (2000 participants registered, of which only 365 were active) in the system is much higher than the number of applications submitted by inventors for review (40 patents, all from large companies). This emphasizes the uneven participation of actors in the system and adduces concerns about the system's ability to ensure sustainable participation by both inventors and external actors (submitters).

4. New Emerging Technologies: A challenge in Europe

In Europe, worries about stakeholder involvement within the patent system date back to 1998, when the European Union (EU) adopted the Biotechnology Patenting Directive 98/44 (BPD). In sharp contrast to the traditional practice of patent law, which has mainly been concerned with machines and engineering challenges, the BPD brought new types of human intervention into the patent arena, often termed "biological material" and "living matter" (EU, 1998). These areas include gene sequences, cells, genetically modified organisms and other biological compounds (Schneider, 2009). The BPD provided for the use of modern biotechnology techniques that focus on the manipulation of biological material (including those involving materials of human origin) using genetic engineering. Therefore, from its beginning the harmonization and the patentability of the new technologies dictated the involvement of a variety of actors.

On the one hand, industry has claimed that only the adequate protection of biotechnology inventions will make research and development profitable: *e.g.* submissions by the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Association for Bioindustries (EuropaBio), and other industrial and trade associations part of the Forum for European Bio-Industry Coordination, (Salter and Jones, 2002).

On the other hand, activist groups have claimed that patenting organisms and modifications of animals or the human genome are regarded as unethical, immoral and may place at risk farmers in the developing world and indigenous peoples: *e.g.* submissions by Greenpeace, Genetics Resources Action International, Rural Advancement Foundation International, the German Protestant Church, the European Ecumenical Commission for Church and Society, ActionAid. These activists were also supported by the Green Party Members of the European Parliament (MEPs), who claimed that the new legislation would lead to monopoly rights being granted that would cause the commercialization of nature, biopiracy and high licensing fees, which would make medical treatment immensely expensive (Thaker, 2003).

[8] Allen,N. et.al. "Peer to Patent: First Anniversary Report" 2008. The Centre for Patent Innovation.1-37. Available at: http://dotank.nyls.edu/communitypatent/P2Panniversaryreport.pdf [Assessed May, 2010]

In this way, patenting in the field of genetics has drawn together a large number of representatives, laypeople and special interest groups to challenge the legitimacy of biotechnology inventions. Developments in genetics have also led to major debates between the EU institutions and various civil society and scientific bodies. The BPD was initially conceived as a purely technical operation, but it took ten years for the Commission, the Council, the European Parliament,[9] and a range of advocacy groups to resolve issues concerning whether human cells, genes, and isolated parts of the human body (including gene sequences) should be considered patentable objects (Andreasen, 2009). The implementation of the BPD in 1998 brought many changes to EPO practice. For the first time, the BPD specified the ordre public and morality exceptions, and addressed the patentability of the human body and parts isolated from it. The BPD introduced a new basis for the protection of biotechnology inventions. Art. 5 and 6 BPD are important since they provide a list of examples of inventions that can (or cannot) be patented (Art. 5 BPD), and of inventions for which the commercial exploitation could be considered contrary to ordre public or morality (Art. 6 BPD), (EU 1998).

Most importantly, it is not the intention that the BPD should affect the basis of patent law (*i.e.* patent criteria, settlement of infringements), nor does it create the authority to grant patents; rather, it is intended to determine explicitly what biotechnological inventions Member States shall protect under their national patent laws (Soini et al., 2008). The conceptualization of the BPD articles (*e.g.* whether "research cloning" should be classified as "cloning" or whether embryos should be classified as "human beings"), the scope of patents in critical fields, and the interpretation of how claims may translate into potential products/processes, is left to the EPO's expertise (Schneider, 2009). Indeed, developments in biotechnology and human genetics have introduced a need for the patent examiners to evaluate applications by weighing their impact on ordre public and morality as well. This requires the availability of a degree of expertise that is not represented in patent offices.[10]

The EPO's current practice reveals that the examination and exclusion of genetically engineered products or human gene sequences is still determined by the use of standard patentability principles, and no specific test is applied to biotechnology inventions. This practice has started to bring many challenges to the examination process, since applicants are filing broad patent applications, involving extensive biological sequence information for each individual claim without clearly disclosing the useful functions that these inventions could perform (Andrew, 2002; Guellec et al., 2007). In this way, the assessment of gene patents and the granting of high-quality patents for inventions that provide a specific, credible industrial application, and are novel and non-obvious to the person skilled in the art, has proved to be difficult at times.

[9] In the case of human genetics, EP has been more sceptical than the Commission about the potential development of these new technologies. As such, during the periods of 1898, 1973, 1997, 1998 and 2000, the EP issued various resolutions on the ethical and legal problems of genetic engineering, and on the legal status of the human embryo, requiring the Member States to prohibit any gene transfer to human germ line cells and to ban the cloning of human beings. These issues also led to extended debates on establishing BPD 98/44 EC.
See: Salter, B., Jones, M. "Regulating human genetics: The changing politics of biotechnology governance in the European Union", 4 Health, Risk & Society 325-340 (2002)

[10] *See also*: Nuffield Council on Bioethics. "The Ethics of Patenting DNA" (2002).
Available from: http://www.nuffieldbioethics.org/patenting-dna [Accessed October, 2010]

It is relatively difficult for the gene sequences to fulfill some of the patentability criteria as they already exist in nature, or there is failure to prove their applicability. Above all, information on gene patents cannot be retrieved easily and in good time. According to USPTO estimates, a search of 100 sequences requires approximately 15 hours of computing time, whereas it takes 65 hours of examiner time to evaluate these search results. Moreover, to provide a qualitative expertise to patent applications in the field of gene sequences, even for a small number of applications, an enormous number of senior-level staff would be need, which obviously is far beyond the working capacity and time-frame within which examiners operate (Ganguli, 2001). These challenges have made the field of gene patents the topic of many heated discussions and intense scrutiny from a number of actors, both in Europe and around the world. However, there are no empirical analyses to date of the way these external actors have been incorporated within the patent prosecution process and whether they can provide a means by which the patent examiners can issue high quality patents.

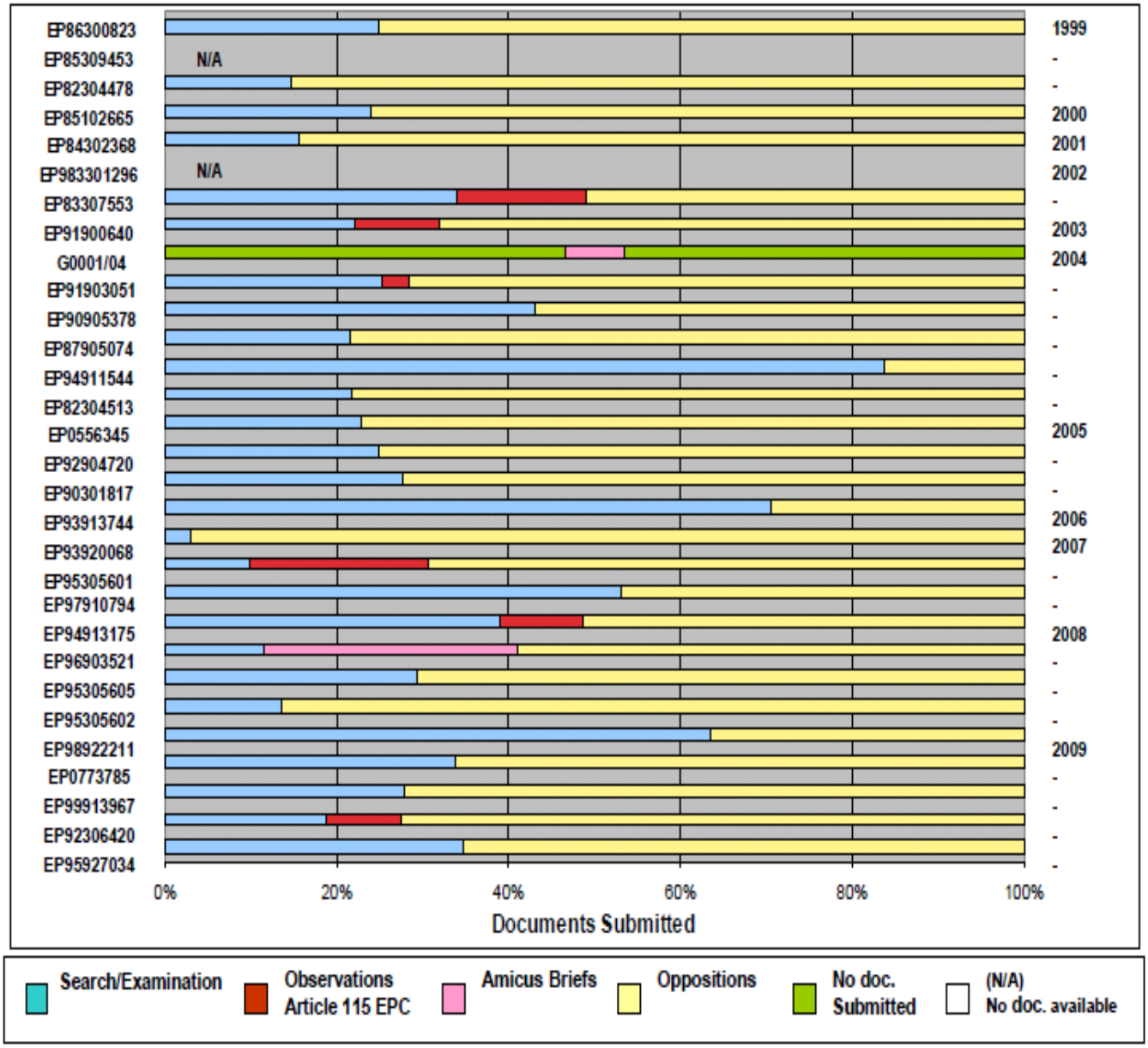
4a) Empirical Evidence on Human Gene Patents

To assess the participation of various actors within the patent prosecution process we started searching the Westlaw International Database. Using this database, we identified patent opposition cases involving human gene patents, including declaratory judgment actions filed by the plaintiff and the Opposition Division. We began by looking at the European Patent Report within the Westlaw International Database, searching for patents that included the keywords “gene & patent & opposition” in the claims or patent application abstract, in the notices of opposition that had been filed, and in the decision that had been made. The search results gave us 38 patent opposition cases dealing with gene patents (including plants and animals) for the period 1999-2009. To narrow down our search scope to human gene patents, we used the terms “human & gene” as the main locators within the results, and retrieved 13 patent opposition cases dealing with human genetics (*i.e.* vectors used for the transfer of genes from one organism to another, therapeutic proteins, genetic testing, DNA sequences, gene therapy, and human stem cells).

Bearing in mind the relatively small number of cases we retrieved on the first attempt to define human gene patent opposition cases, we conducted a second search, this time of the EPO Board of Appeal Database. To provide additional data to our previous hits from the Westlaw International Database, we searched the EBOA decisions Database looking for any patent with respect to which a notice of opposition had been filed and with claims that included any of the following terms: “human gene” *or* “DNA” *or* “human stem cells” *or* “gene sequence”. This search resulted in many hits, but we focused on the patent cases which, according to the EBOA Database, had a higher ranking of hits within their documents. In particular, we found 17 patent opposition cases in this database (30 cases in total from both databases) (*see* Table. 1.1). However, since neither the Westlaw International Database nor the EBOA Database provided us with detailed data on the patent examination proceedings and the actors involved from the search/examination phase up to the final decision, we searched the EPO’s Register Plus and the esp@cenet database. These databases provide detailed information on the

legal status of the European patent applications as well as the documents submitted during all phases of the patent prosecution process.
We acknowledge that this combination of searches does not represent every case on human gene patent prosecution, but we believe they give a clear picture of actors' participation in the examination process, and the impact they have had on the Examination Division's decision (*i.e.* to revoke or grant the application).

Table 1.1. Documents submitted during all phases of the patent prosecution process

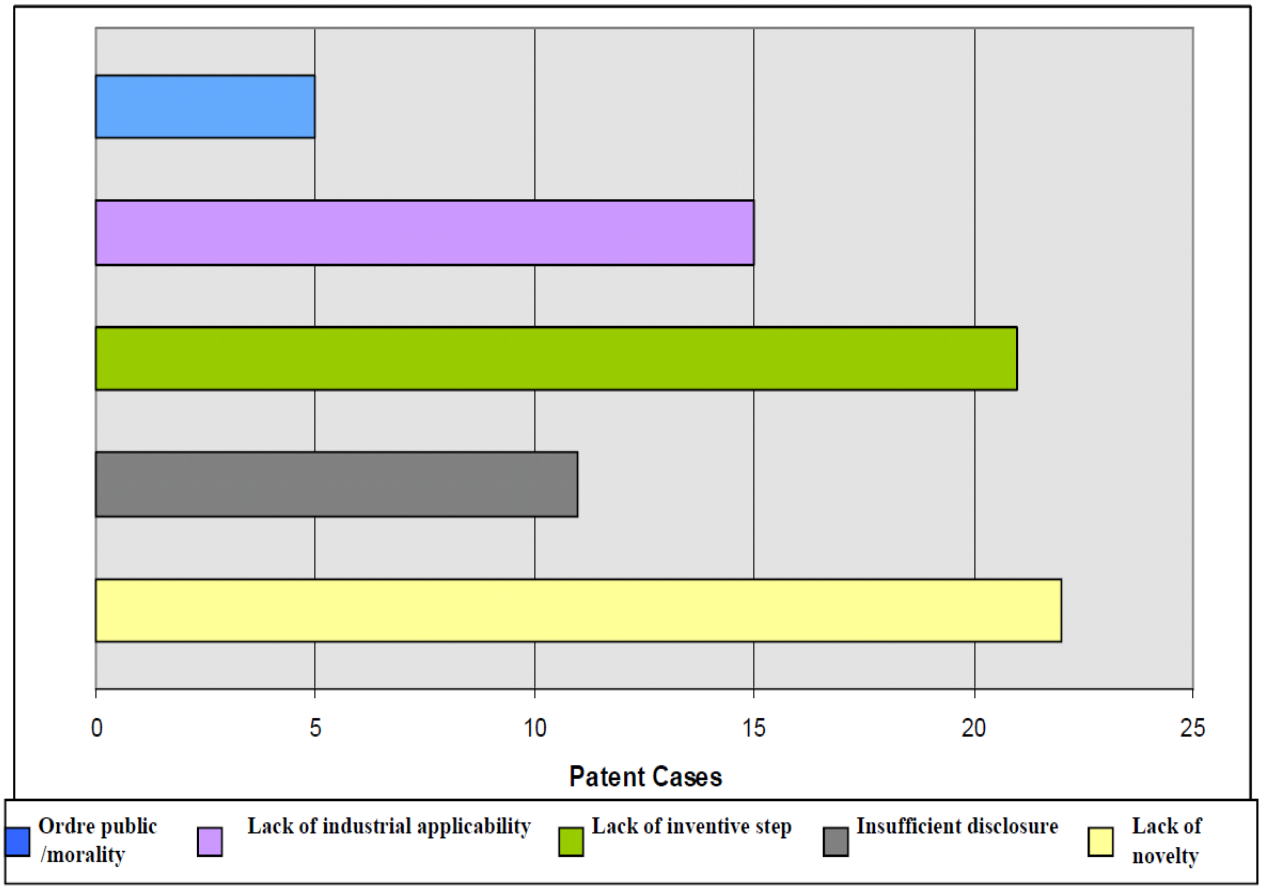


Source: Authors' reprocessing of data retrieved from Westlaw International Database, esp@cenet and EBOA

Our study's findings confirm that third-party participation differs considerably as between the pre- and post-grant phases. Pre-grant patent observations pursuant to Art. 115 EPC are submitted only in a limited number of cases (viz. EP92306420; EP94913175; EP95305601; EP91900640; EP91903051; EP83307553), whereas post-grant oppositions have been filed in every case (*see* Table 1.1 and 1.3).

Comparing the intensity of actor involvement in all phases of patent prosecution process, post-grant oppositions are evidently more dynamic than pre-grant patent observation activities. However, it is interesting to note that the reverse results are observed when it comes to the variety of actors involved. The pre-grant patent observation phase includes a variety of actors from different sectors (*e.g.* patent attorneys, patent professionals, research institutions, special interest and religious groups, medical organizations, patients etc.), whereas post-grant observations are entered by only a limited number of actors and reveal a growing disagreement on patent practices between private actors (research centres-universities and companies).

Table.1.2. Grounds on which patent applications are opposed



Source: Authors' reprocessing of data retrieved from Westlaw International Database, esp@cenet and EBOA

In most cases (Tables 1.2 and 1.3), observers and opponents argue that gene patent applications hardly meet the patentability requirements. These parties argue that the claimed inventions are not novel, do not involve an inventive step, and fail to provide industrial applicability. This evidence also supports the arguments made in foregoing sections that, since applicants have the tendency to file broad patents, they usually fail clearly to disclose the inventions and their application. In some cases, mainly in those applications where pre-grant observations are mostly encountered, third parties argue that patent applications are contrary to the ordre public or morality. This emphasizes that observers have focused not only on the novelty of certain inventions but also the accuracy, safety and usefulness of certain products and processes. However, our empirical evidence still shows that third-party observations (pursuant to Art. 115 EPC) have had a marginal effect on the patentability decisions on numerous inventions in the field of gene technology (*see* Table.1.3).

Table 1.3 Third party "pre-grant" observations at the EPO's patent prosecution process

Patent Application **- Applicants** **- Opponents**	***Observations filed by third parties:*** ***a) Using (Art.115 EPC)*** ***b) In the form of Amicus Curiae Briefs***	***Grounds for filing the observation and/ or oppositions***	***Patent granted OR revoked after the Search Examination Process***	**Decision of the EBOA after *Oppositions were filed***
EP95305601 **Applicant:** -Myriad Genetics, Inc., -University of Utah Research Foundation **Opponent (s):** - Institut Curie - Assistance Publique-Hopitaux de Paris; -Institut Gustave Roussy-IGR (France) - Belgian Society of Human Genetics et al; - Vereniging van Stichtingen Klinische Genetics (The Netherlands) -Danish Society for Medical Genetics (Denmark) -Deutsche Gesellshchaft für Humangenetik (Germany) - State of Netherlands (Dutch Ministry of Health) - National Center for Scientific Research Demokritos (Greece) - British Society of Human Genetics - Austrian Society for Human Genetics - Czech Republic (Society of Medical Genetics) - Societa Italiana di Genetica Umana - -Social Party of Switzerland - Swiss Society of Medical Genetics - Swiss Cancer Research Institute -Greenpeace e.V.et al (Germany and Austria) - Dr. Wilhelms, Rolf E. (Germany)	**Observations pursuant to Article 115 were filed by :** **Individuals representing national institutions, research institutes, scientific societies and interest groups:** - Representatives from the University of Edinburgh; TU Darmstadt; Internists ; "Kommission Okologie und Bioethik Okumenisches"; Representatives from the University of Munchen; "Interdisziplinären Gesellschaft für Umweltmedizin"; International Physicians for the Prevention of Nuclear War ; Association ECOROPA (European Ecological Action); Representatives from the University of Essen; Representatives from the University of Bonn; Punlzistin Freiburg, Bergkirchen; Association of Self-Help Groups and Human Genetics; Institute for Human Genetics (Germany); Members of German Bundestag; Genetic Interest Group; "Forum Christlicher Frauen in Europa" **Patient Organizations**: - Germany: ("Arbeitskreis Leben mit Mukoviszidose"; "Arbeitsgemeninschaft der Selbsthilfegruppen und Humangenetiker" ; "Bundesvereingung Lebenshilfe fur Menschen mit geistiger Behinderung e.V"; "Crystische Fibrose Bundesverband e.V"; "Deutscher Diabetiker-Bund e.V"; "Deutsche Hamophiliegesellschaft zur Bekampfung von Blutungskrankheiten e..V"; "Deutsche Huntington-Hilfe e.V"; "Deutsche Leukamie Forschungshilfe-Action fur krebskranke Kinder e.V"; "Dachverband") - UK: (Lissencephaly Contract Group; Neuro-Fibroma-Tosis Association ; The Pseudoxanthoma Elasticum Support Group ; The Jennifer Trust for Spinal Muscular Atrophy; Telangiaectasia Self Helf Group). **European Organizations from the Field of Medicine**: -German Society of Human Genetics; British Society of Human Genetics; German Medical Association; Austrian Medical Association; World Medical Association; EUROCHORD (Permanent Representation of Doctors in the EU); UK Clinical Molecular Genetics Society; IDO Inherited Disorders Organization Ireland; Autisme - Europe-Osteogenesis Imperfecta Federation Europe; Alzheimer's Disease Society ; Association for Glucogen Storage Disease; Genetic Interest Group; Gorlin Syndrome, International Autistic Research Organisation; Microcephaly Support Group; Neurofibromatosis Association; PXE Support Group, Society for Mucopolysaccharide Diseases; Sticker Syndrome Support Group; Alliance of Self-support Group and Human Geneticists; ECOBP-European Campaign on Biotechnology Patents	-Subject matter not Patentable under Rule 23 d (c) EPC -Patent application does not disclose the invention in a sufficient and clear manner for it to be carried out by a person skilled in the art (Art. 100 (b)/83 EPC) - The invention is contrary to ordre public or morality (Art. 53 (a) EPC)	**Patent Granted**	**Decision to maintain the patent in an amended form**

EP91903051 **Applicant**: Applied Research System , ARS Holding Mv **Opponent**: Gruppo Lepetit SpA Cell Genesys, Inc.	**Observations pursuant to Article 115 were filed by :** Mewburn Ellis (Chartered Patent Agents)	- Lack of inventive step (Arts. 52 (1), 56 (EPC))	**Patent Granted**	**Patent Revoked**
EP94913175 **Applicant**: -University Court Of The University Of Edinburgh **Opponent**: Institut Pasteur	**Observations pursuant to Article 115 were filed by:** Individuals	- Lack of novelty (Art. 100 (a)/54 EPC - Lack of inventive step (Arts. 52 (1) , 56 (EPC)) - Lack of sufficient disclosure (Art.100 (b)/83 EPC)	**Patent Granted**	**Decision to maintain the patent in an amended form**
EP96903521 **Applicant:** WisconsinAlumni Research Foundation (WARF) **Opposition (s):** Appeal filed by Wisconsin Alumni Research Foundation against the Examination Decision to refuse the patent application	**Approximately 200 Amicus Curiae Briefs** pursuant to Article 11 (b) of the Rules of Procedure of the Enlarged Board of Appeal were received from: interested circles of the public, Members of the European Parliament (MEP); interest groups; NGOs and religious community; patent attorneys and patent professionals. **MEP**: German Bundestag ; The European Parliament; **Patent Attorneys**; Scientists /Patent Professionals ; European Center for Law and Justice **Professionals & Research Institutions:** Professionals from the Medical Sector; University of Wien; University of Ghent; University of Basel; University of Tubingen; The Scottish Council of Human Bioethics (SCHB); "Basler Appell Gegentechnologie"; Environmental Protection Agency (EPA); Institute of Medical Ethics and Bioethics **Religious Groups:** (e.g.Kolpingsfamilie St. Aloysius; "Seelsorgeeinheit Riedlingen"; "Katholisches Pfarramt ST.Matinus und St. Maria"; "Christian Action Research and Education"; "KAB.ST.Patrokli Soest", "Katholisches Buru Niedersachsen" **Interest Groups:** Bioindustry Association (BIA)-UK Greenpeace e.V.; "KOLPING Diozesanverband Bamberg" AOL Fax & Voice; "Jungbauernschaft Landjugend Bezirk Kufstein"; "AIIPPI (Internationale Vereinigung fur den schutz des geistigene eigentums)"; Women's Group-Korean WomenLink; Italian Political Association (SOLIDARIETA, Liberta, Giustizia e Pace); Forum-Info/Wien "No Patents on Life"; ALFA "Aktion Lebensrecht fur Alle Regionalverband Rosenheim"; **Industry**	- The claimed inventions not patentable under Rule 23 d (c) EPC - The invention is contrary to ordre public or morality (Art. 53 (a) EPC)	**Patent Revoked**	**Patent application is deemed to be withdrawn**

EP91900640 **Applicant:** Cell Genesys, Inc. **Opponent:** - Applied Research Systems Ars Holding Nv - Institut Pasteur Roche Diagnostics GmbH	**Observations pursuant to Article 115 were filed by :** Private entities: "Societe De Conseils En Properiete Industrielle"; "Wuesthoff and Wuesthoff : Patent und Rechtsanwalte"	- Lack of novelty (Art. 100 (a)/54 EPC - Lack of inventive step (Arts.52 (1) , 56 (EPC))	**Patent Granted**	**Decision to maintain the patent in an amended form**
EP92306420 **Applicant**: Welcome Foundation Limited **Opponent**: - Crucell Holland B.V. - Medimmune Limited Abbott Laboratories	**Observations pursuant to Article 115 were filed and submitted to the EPO without sender's address, name or signature.** As such, the admissibility of the third party's observations under Article 115 EPC was contested by the respondent. However, it is essential to note that third parties' observations overlapped with the arguments of the Opponents.	- Lack of novelty (Art. 100 (a)/54 EPC - Lack of inventive step (Arts. 52 (1) , 56 (EPC)) - Lack of sufficient disclosure (Art.100 (b)/83 EPC)	**Patent Granted**	**Decision to maintain the patent in an amended form**
PPG,Disclaimer G0001/04 (Opinion in relation to the application of the diagnostic methods to the human body)	**Amicus Curiae Briefs** pursuant to Article 11 (b) of the Rules of Procedure of the Enlarged Board of Appeal were received from: "The Fédération Internationale des Conseils en Propriété Industrielle (FICPI)"; The European Society of Human Genetics (ESHG); Mr. Simon Kremer of Mewburn Ellis; European Patent Attorneys, London; Dr. H.-P. Pfeifer on behalf of Roche Diagnostics; Philips Intellectual Property & Standards; Mr. Andrew Sheard on behalf of Amersham plc, now trading as GE Healthcare; Bio-Sciences, Siemens AG; Praxis Dr. med. Ulrich Kübler; "Società Italiana Brevetti"; The Institute of Professional Representatives before the European Patent Office (EPI)	Statements - in favor of a narrow interpretation of the patent exemption for diagnostic methods under Art. 52(4) EPC - in favor of a broad interpretation of the patent exemption	// /	-"Art.52(4) EPC does not require a specific type and intensity of interaction with the human or animal body - the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision must satisfy the criterion "practised on the human or animal body"

Source: Authors' reprocessing of data retrieved from Westlaw International Database, esp@cenet and EBOA

In particular, in the case of Myriad Genetics' European Patent (EP95305601) on the BRCA1 gene, more than 100 observations were submitted to the Examination Division from a variety of actors (*e.g.* hospitals, scientists, research laboratories, physicians,

patient organizations), who claimed that the patent application: was not novel (since many other methods already existed for diagnosing a predisposition to breast cancer); lacked inventiveness (since the patentees mainly benefited from prior research conducted by an international consortium on BRCA in collaboration with patients and families); and lacked sufficient and adequate description and disclosure of the claimed invention (Andrew, 2002).However, a patent was still granted, which led to many opposition filings, appeals and long debates among stakeholders until a decision was made to amend and keep the patent in amended form.

Other patent cases, such as EP83307553 (on molecular cloning and characterization of a further gene sequence coding for human relaxin); EP91903051 (on a method for gene expression by way of homologous recombination); EP94913175 (on a method for inserting a heterologous gene coding sequence into a targeted endogenous gene) and EP91900640 (on a method used to transfer genes from one organism to another), reveal that third parties have submitted fewer observations as compared to the EP95305601, and their impact on the decision of the Examination Division continues to be marginal.

The case of EP92306420 (on a process for the production of a recombinant human antibody) also provides important information on the way third-party observations are filed. In this case observations were submitted inappropriately, providing inputs with no value to patent examiners.

To understand and observe the interests of third parties in providing information on the patentability of new inventions, we also looked at the WARF patent case (EP96903521). This application was refused in 2004 by the EPO's Examination Division on morality grounds. Subsequently, WARF appealed and the Technical Board of Appeal (TBA) which heard the appeal referred the case with questions to the Enlarged Board. Pursuant to Art.11 (b), EBOA requested parties to provide opinions on the WARF case (Salter, 2009). Following this request, third parties submitted more than 200 *amicus curiae* briefs (Art. 120 EPC) expressing their support for or objections to the patentability of human embryonic stem cells. Part of our analysis of human gene patents included the G0001/4 Oppinion, in which a number of amicus curiae briefs were filed by a number of actors expressing opinions on the application of diagnostic methods to the human body (*see* Table 1.3). Both of these cases are important to our study as they emphasize the willingness of third parties to provide opinions and observations on the protection of human gene inventions.

5. Policy Recommendations and Conclusions

What do the uses of Art. 115 EPC on human gene patents tell us? The controversy about these sensitive inventions reflects a growing social awareness of the uncertainties on which patent examiners base their decisions. In contrast to past practice, in which patenting issues were merely considered as part of a technical process, biopatent developments have come to attract greater public participation. Human gene patents and the associated disputes have drawn together a large number of scientific community

representatives, laypeople and special interest groups to challenge the legitimacy of the EPO's granting practice.

The BPD has settled the legality of patenting biotechnology, but it has failed to satisfy certain stakeholders, who have used patent prosecution as a downstream mechanism to influence the scope of the protection of new, emerging technologies. As emphasized in Section 4, case-law evidence in human gene patents clearly reflects that third-party participation has not proved to have a demonstrable impact. By means of Art. 115 EPC, third parties have submitted a number of observations on the patentability of inventions.

Observations have been filed in different ways: a) observations with no value to the patent examiner (*i.e.* EP92306420); b) observations filed only by a limited number of private parties (*i.e.* EP94913175; EP91903051; EP91900640); and c) numerous observations filed by third parties from different sectors (*i.e.* EP95305601; EP96903521). This practice has caused patent examiners either to have no information or to be overwhelmed with dozens of marginal observations on patentability, but not even a handful of references that could contribute to the granting of high quality patents. Indeed, if the EPO is to improve the quality of the patents it grants, it should make the search and examination process a forum for lively re-engagement by creating a route for the participation of knowledgeable bodies, which have knowledge of genetic engineering and human genetics issues, include a wide range of actors within their network, and represent the common interests of the society.

The disputes and dilemmas associated with the protection and regulation of biotechnology inventions have already led the establishment of various forms of knowledgeable bodies acting as biotechnology information agents to provide information on new technology inventions, regulate advice on the trajectories of sensitive technologies, and foster innovation through networking efforts and collaboration with other specialist entities in the field. For instance, at the national level there are numerous *scientific societies and research institutions* (*e.g.* Austrian Forum Gene technology and Us; Austrian Society for Genetics and Gene Technology; German Society for Biochemistry and Molecular Biology; German Society of Human Genetics; the Netherlands Society for Biotechnology; the Spanish Society of Biotechnology; Royal Society of UK; the British Society of Human Genetics; Flanders Interuniversity Institute for Biotechnology; the Swedish Royal Academy of Science), *environmental interest groups* (*e.g.* Greenpeace, the Environmentalist NGO group "Friends of the Earth") and *advisory bodies* (*e.g.* the Danish Board of Technology and the Danish Council of Ethics; the French Commission of Bimolecular Genetics; the Commission of Genetic Resources; the Commission of Genetic Improvements, and the Committee of Ethics; the Secretariat for Biotechnology Information in Germany; the German Council of National Ethics; the National Ethics Committee of Luxembourg; the Royal Academy of Arts and Sciences in Netherlands; the Swedish Gene Technology Advisory Board; the Human Genetics Commission in UK; the UK Nuffield Council of Bioethics) (*see more*: Moses et.al.,2002; Soini et al., 2008).

These societies have close joint ventures with many other specialists drawn from the universities, research institutions, industry, health professionals in medical research and

genetic services, as well as non-government entities that establish networks between scientists and society at large. It is interesting to note that these groups have been active nationally, providing information, workshops, forums, guidelines and position papers on life science technologies, including issues of genetic engineering, human genetics, stem cells, biochemistry, molecular bioscience, medicine, etc. However, their participation in the patent prosecution process remains marginal. Our empirical evidence (see Table 1.3.) shows that, of all the societies mentioned above, the only active ones are the German Society of Human Genetics; the British Society of Human Genetics and Greenpeace.

At the European level, biotechnology – human gene technology in particular – has attracted the attention of certain advisory bodies and learned societies. The creation of the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology (GAEIB) (afterwards renamed the European Group on Ethics in Science and New Technologies (EGE)) has been very valuable to the development of biotechnology. The EGE's mission is to provide opinions after considering and comparing the work of other national ethics committees, as well as other international and European legal instruments. As such, EGE aims to establish fundamental ethical principles, support the right of civil society and advise "Community authorities responsible for regulating the market to account for public aspirations in the various aspects of their lives: consumers, workers, parents, patients etc." (EGE, 2001) From the beginning, the GAEIB's creation changed the representation of stakeholders' interests in life science technologies. During its initial development stages GAEIB played a crucial role in advising the Commission that effective developments in EU biotechnology require extensive coordination with numerous stakeholders both inside and outside the Commission (Daviter, 2009). Following the GAEIB, EGE has continuously provided advice in the form of "opinions" at the request of the President or in certain cases independently. In July 1997 the EP also required the EGE to guarantee Parliament's involvements in its ethical deliberations. The EGE's opinions have been important in the development of the Biotechnology Directive and the European Research Framework Programme on the use of human embryos, with which the role of the bioethics gained institutional recognition in the policy making process. The rules of the BPD also advocate for the inclusion of the EGE in the evaluation of all ethical aspects of biotechnology and the provision of consultancy on sensitive issues, including patent law (Article 7 and Recital 44) (Salter and Jones, 2002). These requirements have led the EGE to become an active player in the field of human genetics, providing opinions on gene therapy, cloning and the genetic modification of animals, genetic diagnosis, human tissue banking, etc.

In Europe, the European Society of Human Genetics (ESHG) is among the best-known learned societies in Europe. ESHG was established in 1967 and has continuously provided recommendations and reports on gene patenting, diagnostic testing and public health aspects (see Aymé et al., 2008; Soini et al., 2008). Most importantly, ESHG is known for its initiatives in promoting research, ensuring high standards and fostering the debate in the human genetics community on human and medical genetics, while providing background documents and recommendations (*e.g.* "The European Journal of Human Genetics"; "Patenting and licensing in genetic testing: ethical, legal and social

issues", 2008; "Genetic testing and common disorders: proposed recommendations of the European Society of Human Genetics", 2009). Among the most important committees of the ESHG are: the Public and Professional Policy Committee (PPPC) and Patenting and Licensing Committee (PLC). In 2007, PPPC and PLC, at the request of the ESHG, looked at the issue of patenting in relation to genetic testing while analyzing the most contemporary literature on patenting and human genes, and recent reports produced by the Council of Europe, OECD, UNESCO and other international organizations. These documents were reviewed by several experts, such as academic lawyers, experts of the EPO and NGOs, and were published in the European Journal of Human Genetics (ESHG, 2007 and 2008). ESHG has been in regular contact with different directorates of the EU Commission and scientific organizations, as well as major diagnostic biotechnology companies, discussing complex issues related to human genetics.[11] In regard to the patent prosecution process, in 2004 ESHG submitted opinions to the EBOA in relation to the interpretation of the patent exemption for diagnostic methods under Art. 52 (4) EPC (*see* Table 1.3), and in 2006 ESHG representatives filed oppositions to the BRCA1 gene patents.[12]

In addition, ESHG has been collaborating with other well-known organs in the biotechnology area. For instance, the European Federation of Biotechnology (EFB) is another independent learned society that consists of 50 members from all EU and other European countries, and 90 scientific societies. Its members are drawn from industry, government, environmental and research organizations, as well as practitioners. As such, the EFB has become a federation of "National biotechnology associations, learned societies, universities, scientific institutes, biotechnology companies and individual biotechnologists, working to promote biotechnology throughout Europe".[13] EFB comprises six task groups, among which are the Task Group on Innovation, Safety in Biotechnology, and Public Perception in Biotechnology. The aim of the EFB and its task groups is to provide an interdisciplinary international forum, foster public understanding and collaboration with scientists, and promote research and innovation on various subjects including biotechnology, patents, nanotechnology and plant biodiversity, inter alia. In addition, the EFB also aims to provide guidelines, position papers, reviews and expertise in life science technologies.[14]

Taking into consideration the potential of the above knowledge communities (learned societies and advisory bodies) to provide information on biotechnology and human genetics, it is important that the EPO makes use of these entities by establishing the right incentives for them to contribute to the patent examination process. EPO should

[11] In 1991 ESHG also contributed to the creation of the European Alliance of Genetic (later called as: European Alliance of Patient and Parent Organisations for Genetic Services and Innovation in Medicine), which comprises national genetic alliances and disease-specific patient groups that have an interest in innovative medicine, genetics and biotechnology. This alliance aims to provide position papers and statements on various subjects covering diagnosis, stem cells, gene and tissue therapy, bio-banks testing, patenting and IP, inter alia. *See:* European Society of Human Genetics. "Are we there yet?", 2007. ESHG Newsletter No.16

[12] Gert Matthijs, one of the members of the ESHG, submitted observations and oppositions claiming the invalidity of the Myriad patent application.

[13] *See also*: "The European Federation of Biotechnology". Available at: http://www.efbweb.org/who/organi1.htm

[14] *See also*: Moses, V.et al. "Biotechnology: Educating the European Public-final report", 2002. Brussels, Belgium: European Commission, 246-251

have an optimized number of carefully selected external actors, effectively managed, with whom collaborations could be developed. In our view, EPO can improve the quality of its patents and its collaboration with third parties by establishing a lively pre-grant patent advisory forum that operates on a regular or a case-by-case specific basis, for the most sensitive cases only, and will enable learned societies and advisory bodies to analyze patent application claims, provide information on the potential of inventions and share expertise. Professional or learned societies, for instance, can issue reports on the patentability of inventions and their potential for the state of the art, to simplify the examination process and broaden the expertise on new technology developments. This would assist EPO to be more selective when granting patents, to reduce backlogs and costly litigation procedures. Most importantly, since these entities differ in their level of expertise and prior-art knowledge of genetics, as well as their geographic representation, an advisory forum would inform the EPO examiners about the implications that certain inventions may have in other countries, and on the new genetic mechanisms that are likely to be protected in future. In this way, a pre-grant advisory forum would lead to a multidisciplinary foresight and an ex-ante patent impact assessment, would provide additional resources to the examiners, and ensure ongoing deliberations and better collaboration among experts on the patentability of numerous subjects. Most importantly, it would improve the analytical capacity of the patent authorities and keep the EPO abreast of the dynamic socio-economic debate on patentability.

References

Akers, N., 2000. The referencing of prior art documents in European patents and applications. *World Patent Information* 22: 309-315

Andrew, L., 2002. Genes and patent policy: rethinking intellectual property rights. *Nature Reviews* 3: 803-808

Andreasen, M., 2009. Two stories about biotech patenting from the “silent majority” in Europe. *Public Understanding of Science*, 19 (3): 355-371

Aymé, S.et al. 2008. Patenting and licensing in genetic testing. *European Journal of Human Genetics*, 16: S3–S9

Brooks, H., Johnson, R.,1991. Comments: Public policy issues. In: Davis, B. (ed). *The genetic revolution: Scientific prospects and public perceptions*. Baltimore, MD: Johns Hopkins University Press

Brownsword, R., 2008. *Rights, Regulation and the Technological Revolution*. USA, NY: Oxford University Press.

Burke, P., Reitzig, M., 2007. Measuring patent assessment quality-Analyzing the degree and kind of (in) consistency in patent offices’ decision making. *Research Policy*, 36 (9): 1404-1430.

Cowan, R. et al., 2007. *Policy options for the improvement of the European patent system*. STOA Report/FWC/2005-28. Brussels: European Parliament.

Cohen, S., Morgan, G.,Royle, M., 2008. Litigating biotech patents in Europe, *Intellectual Asset Management Magazine*. Available from: http://www.iam-magazine.com [Accessed April 2010]

Davier, F., 2009. Schattscheider in Brussels: How policy conflict reshaped the biotechnology agenda in the European Union. *West European Politics*, 32 (6): 118-1139

Duane, M., 2008. Lending a hand: The need for public participation in patent examination and beyond. *Chicago-Kent Journal of Intellectual Property*, 50-74

European Union., 1998. Directive 98/44/EC of July 6, 1998 on the Legal Protection of biotechnological inventions. *Official Journal* L213, 30 (7): 13-21

European Society of Human Genetics., 2007. Are we there yet? ESHG Newsletter No.16

European Society of Human Genetics., 2008. ESHG: the Voice of Human Genetics in Europe. ESHG Newsletter No.17

Edfjäll, C., 2007. European patent information 2007: EPO policy reformulated. *World Patent Information*. 30 (3): 206–211

European Commission, 2008. Industrial property rights strategy. COM(2008) 465. Brussels: DG MARKT

Elsmore, M. 2009. Quality and Quantity: Can We Have Both Within the European Patent System. *ERA-Forum*. 10: 215–230

European Patent Office., 2009. Annual Report 2008. Available from: http://www.epo.org/about-us/office/annual-reports/2008.html [Accessed February 2010]

Guellec, D., van Pottelsberghe, B., 2007. *The Economics of the European Patent System*. USA, NY: Oxford University Press Inc.

Guellec, D., van. Pottlesberghe, B., Zeebruck, N., 2007. Patent as a market instrument. In: Guellec, D., van Pottelsberghe, B., 2007. *The Economics of the European Patent System*. USA, NY: Oxford University Press Inc.

Ganguli, P., 2001. Intellectual property rights: mothering innovations to markets. *World Patent Information* 22: 43-52

Harhoff, D., 2009. *Economic cost-benefit analysis of a unified and integrated European Patent Litigation System*. Germany: EU, Tender No. MARKT/2008/06/D.

Holzer, W., 2005. *Patent litigation in Europe-an Adventure*. Seminar on IPR Protection in Europe: Reaching the European Market, July 19-20, 2005, Bangkok

Harmon, S., 2006. The rules of re-engagement: The use of patent proceedings to influence the regulation of science 'What the salmon does when comes back downstream', *Intellectual Property Quarterly* 4: 648–66.

Holman, C., 2008. Trends in human gene patent litigation. *Science* 322: 198-199

Kao, A., 2006. Peer Review Of Patents: Can The Public Make The Patent System Better? *Journal of Law, Technology & Policy,* 101-119

Langinier, C., Moschini, G.,2002. The economics of patents: an overview*. Working Paper 02-WP-293.* Iowa State University.

Moses, V.et al., 2002. *Biotechnology: educating the European public-final report*. Brussels, Belgium: European Commission

Noveck, S., 2006. Peer to Patent: Collective intelligence, open review, and patent reform. *Harvard Journal of Law & Technology* 20 (1): 123-161

Philipp, M., 2006. Patent filing and searching: Is deflation in quality the inevitable consequence of hyperinflation in quantity? *World Patent Information*, 20: 117-121

Picciotto, S. 2001. Democratizing the new global public sphere. Available from: http://www.lancs.ac.uk/staff/lwasp/demglobpub.pdf [Accessed August 2010]

Salter, B., Jones, M., 2002. Regulating human genetics: The changing politics of biotechnology governance in the European Union. *Health, Risk & Society* 4 (3): 325-340

Soini, S., Aymé, S., Matthijs, G., 2008. Patenting and licensing in genetic testing: ethical, legal and social issues. *European Journal of Human Genetics* (16): S10-S50

Staff Union of the European Patent Office., 2002. A Quality Strategy for the EPO. SUEPO Working Paper. Available from: http://www.suepo.org/public/quality_quantity/quality2002.pdf [Accessed July 2010]

Schneider, I., 2009. Can patent legislation make a difference? Bringing parliaments and civil society into patent governance. In: Sebastian, H. and Kenneth C.S., eds. *Politics of Intellectual Property*. Edwar Elgar Publishing Inc: UK, 129-157

Schrell, A., Bauser, H., Brunner, H., 2007. Biotechnology patenting policy in the European Union-as exemplified by the development in Germany , *Advances in Biochemical Engineering Biotechnology,* 107: 13-39

Shang, R., 2009. Inter partes reexamination and improving patent quality. *Norwestern Journal of Technology and Intellectual Property* 7 (2): 185-203

Thaker, S., 2003. The criticality of non-market strategies: The European Biotechnology Patents Directive. Available from: www.kellogg.northwestern.edu [Accessed September 2010]

The European Group on Ethics in Science and New Technologies., 2001. On the activities of the European Group on Ethics in Science and New Technologies to the European Commission. General Report. Available from: http://ec.europa.eu/european_group_ethics/publications/docs/rap_en.pdf [Accessed May 2010]

Thomas, J., 2001. The responsibility of the rule maker: Comparative approaches to patent administration reform. Berkley Tech.L.J 17: 727-761

van Pottelsberghe. B., 2009. Lost property: the European patent system and why it doesn't work. *Bruegel Blueprint Series* IX: 3-71

Wagner, R., 2009. Understanding patent quality mechanisms. *University of Pennsylvania Law Review* 157: 1-38

White, K., 2004. An efficient way to improve patent quality for plant varieties. *Northwestern Journal of Technology and Intellectual Property* 3: 9-91.